

## **REMARKS**

1. In response to the Office Action mailed July 6, 2009, Applicants respectfully request reconsideration. Claims 1-6, 8-17, 20, 21, 24-26 and 28-62 were last presented for examination. In the outstanding Office Action, claims 1-6, 8-17, 20, 21, 24-26 and 28-62 were rejected. No claims have been amended, added or cancelled. Upon entry of this paper, claims 1-6, 8-17, 20, 21, 24-26 and 28-62 will be pending in this application. Of these fifty-six (56) claims, four (4) claims (claims 1, 24, 29, and 59) are independent.
2. Based upon the following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

### ***Interview Summary***

3. Applicants thank the Examiner for conducting a telephonic interview in this application with Applicants' representatives on October 14, 2009. During the interview, Applicants' independent claims 1 and 29 were discussed in light of applied references U.S. Patent No. 6,119,044 to Kuzma (hereinafter, "Kuzma") and U.S. Patent No. 5,123,422 to Charvin (hereinafter, "Charvin").
4. During the interview, Applicants' representatives presented arguments that neither Kuzma nor Charvin, individually or in combination, discloses that "said tip member is dimensioned and shaped such that said tip member causes at least a portion of said tip member to operate as a constant-strength cantilever beam," as recited in Applicants' claim 29. The Examiner agreed to reconsider whether Kuzma and Charvin disclose this limitation upon the presentation of a written response. Applicants also presented arguments that neither Kuzma nor Charvin, individually or in combination, discloses "wherein said conical tapered portion of said tip member is dimensioned and shaped such that said conical tapered portion of said tip member prevents substantial foldover of said tip," as recited in Applicants' claim 1.
5. Applicants are thus providing a written response presenting Applicants' arguments, as requested by the Examiner.

***Rejections of claims 1, 24, and 59 under §103***

6. The Examiner rejected claims 1-3, 8, 14-17, 20, 24, 28-30, 32-35, 39, and 45-49 under 35 U.S.C. 103(a) as allegedly unpatentable over U.S. Patent No. 6,119,044 to Kuzma (hereinafter, “Kuzma”) in view of U.S. Patent No. 5,123,422 to Charvin (hereinafter, “Charvin”). Applicants respectfully request reconsideration and withdrawal of these rejections for at least the following reasons.

***Applicants submit that the Examiner has failed to provide adequate factual support for his obviousness conclusion.***

7. Applicants’ claim 1 recites “a tip member comprising a flexible conical tapered portion . . . dimensioned and shaped such that said conical tapered portion of said tip member prevents substantial foldover of said tip when a deflection/impact force is applied to said tip member during implantation into the cochlea.” (See, Applicants’ claim 1, above.)

8. Kuzma is directed to an implantable electrode array that may be inserted into a cochlea. (See, Kuzma, Abstract.) Specifically, Kuzma discloses an electrode array 30 comprising a flexible carrier 36. (See, Kuzma, col. 11, lns. 23-26; and FIG. 4.) Kuzma also teaches that “a soft tip 37 . . . is typically formed from LSR-25 at the very distal tip of the electrode array 30.” (See, Kuzma, col. 11, lns. 39-41; and FIG. 4.)

9. The Examiner appears to assert that soft tip 37 of Kuzma is analogous to the tip member recited in Applicants’ claim 1. (See, Office Action, page 3.) However, the Examiner admits that Kuzma “fails to teach a conical tapered portion tapering and extending distally from the distal end of the electrode array.” (See, Office Action, page 6.) Thus, the Examiner relies upon Charvin in attempting to cure this deficiency of Kuzma.

10. Charvin is directed to “[a]n intra-cochlea electrode carrier.” (See, Charvin, Abstract.) Charvin discloses multiple embodiments of an electrode carrier, each embodiment including a plurality of slits 12 intended to “facilitate bending” of the carrier electrode. (See, Charvin, col. 9, lns. 6-8, 14-16, 22-31, and 36-41; and FIGS. 3-5.) While Charvin does not appear to specifically describe details of a “tip” of the electrode carrier, FIGS. 3-5 each show an electrode carrier that tapers at a distal end thereof. (See, Charvin, FIGS. 3-5, and col. 6, lns. 61-62.)

11. In attempting to cure the above-noted deficiency of Kuzma, the Examiner states that “Charvin teaches that it is known to have a conical tapering at the distal end of an electrode array.” (*See*, Office Action, page 6.) Moreover, the Examiner states that

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kuzma with a conical tapered portion tapering and extending distally from the distal end of the electrode array, since such a modification was known in the art to provide the predictable results of preventing foldover of the tip member, facilitating insertion of the electrode array and providing a more rigid support to facilitate placement, and providing for the electrode array to conform to the natural shape and geometry of the cochlea. (*See*, Office Action, page 6.)

12. Applicants would like to remind the Examiner that the Manual of Patent Examining Procedure (MPEP) states that “[t]he examiner bears the initial burden of ***factually supporting*** any *prima facie* conclusion of obviousness.” (*See*, MPEP § 2142; emphasis added.) Applicants submit that the Examiner fails to provide any factual support for the assertion that the modification proposed by the Examiner, as quoted above, “was known in the art to provide the predictable results of ***preventing foldover of the tip member.***” (*See*, Office Action, page 4.) Specifically, the Examiner does not point to any teaching in Kuzma or Charvin to factually support the above-quoted conclusory statement.

13. In addition, the Examiner appears to propose modifying soft tip 37 of Kuzma to give it a conical tapered shape. Kuzma discloses that “soft tip 37 . . . is typically formed from LSR-25,” which Kuzma teaches “is essentially the same as LSR-70 except that when [LSR-25] cures it is significantly softer, i.e., more pliable.” (*See*, Kuzma, col. 11, lns. 39-40 and 12-14.) In addition, Kuzma discloses that LSR-70 and LSR-25 are each materials from which an electrode array 30 of Kuzma may be made. (*See*, Kuzma, col. 10, ln. 63 through col. 11, ln. 1.) However, the Examiner fails to provide any factual support for the assertion that soft tip 37, once modified to have a conical tapered shape, would “prevent[] substantial foldover of said tip,” as recited in Applicants’ claim 1. Applicants submit that the Examiner provides no evidence that soft tip 37, once modified, would either fold over or not fold over. However, as noted above, Kuzma discloses that soft tip 37 is formed from LSR-25, which is ***significantly softer*** than LSR-70. Thus, Applicants submit that if any inference is to be drawn from soft tip 37, it is that Kuzma

discloses a soft tip 37 that, once modified, would be likely to fold over more readily than a similar tip formed from the LSR-70 material disclosed by Kuzma.

14. Moreover, if the Examiner is relying on his own personal knowledge, Applicant requests that the Examiner provide an affidavit in support of the above-quoted statements under 37 C.F.R. 1.104(d)(2), which states that “[w]hen a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee.” (*See*, 37 C.F.R. 1.104(d)(2).)

15. In addition, referring to soft tip 37 of Kuzma, the Examiner states that “Examiner considers the portion disclosed in section L8 of FIG. 4 to be the tip, which is apparently geometrically incapable of folding over itself.” (*See*, Office Action, page 4.) However, the Examiner proposes *modifying* the shape of soft tip 37 of Kuzma based on Charvin to give soft tip 37 a conical tapered shape. Applicants submit that once the shape of soft tip 37 of Kuzma is modified as proposed by the Examiner, then the Examiner’s above-quoted statement is no longer applicable, since the Examiner proposes modifying *the geometry* (i.e., the shape) of the soft tip. Thus, Applicants submit that the above-quoted statement fails to provide support for the assertion that the modification proposed by the Examiner “was known in the art to provide the predictable results of *preventing foldover of the tip member*.” (*See*, Office Action, page 4; emphasis added.)

16. Additionally, the Examiner states that “Charvin teaches that it is known to have a conical tapering at the distal end of an electrode array as set forth in Figs. 3-5, for providing the predictable results of preventing fold-over of the tip member . . . .” (*See*, Office Action, page 6.) However, the Examiner fails to point to any portion of Charvin that actually teaches that preventing foldover of a tip member is a predictable result of having a conical tapering at a distal end of an electrode array. The above-quoted sentence from the Office Action ends with a citation to column 1, lines 65-66 of Charvin. However, that portion of Charvin fails to support the Examiner’s assertion regarding the prevention of foldover. If the Examiner is relying on his personal knowledge, Applicants request that the Examiner provide an affidavit to that effect in accordance with 37 C.F.R. 1.104(d)(2).

*Applicants submit that the Examiner has failed to meet the requirements for using the exemplary rationale set forth in MPEP § 2143(A).*

17. Applicants thank the Examiner for indicating that “Examiner has set forth a case of obviousness based on combining prior art elements according to known methods to yield predictable results (see MPEP 2143 [EXEMPLARY] RATIONALES (A)).” (*See*, Office Action, page 9.) However, Applicants would like to remind the Examiner that, regarding that rationale, the Manual of Patent Examining Procedure (MPEP) states the following:

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel *must articulate the following*:

(1) a finding that *the prior art included each element claimed*, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. (*See*, MPEP § 2143(A); emphasis added.)

18. The Examiner has combined teachings of Kuzma and Charvin in an attempt to show that the device recited in Applicants’ claim 1, and specifically the recited tip member, would have been obvious. However, Applicants submit that the Examiner cannot rely on “[c]ombining prior art elements according to known methods of yield predictable results” to support the obviousness conclusion that the Examiner has made in this Office Action, (*see*, MPEP § 2143), because the Examiner has not articulated “a finding that *the prior art included each element claimed*.” (*See*, MPEP § 2143(A); emphasis added.) Moreover, Applicants submit that the above-noted finding required by MPEP § 2143(A) does not require the Examiner to show merely that each element would have been *obvious* in light of the prior art, but that “the prior art *included* each element claimed.” (*See*, MPEP § 2143(A); emphasis added.)

19. Applicants submit that the Examiner has not articulated a finding that either Kuzma or Charvin taught “a tip member comprising a flexible conical tapered portion . . . [that] prevents substantial foldover of said tip,” as recited in Applicants’ claim 1. Specifically, the Examiner fails to assert that Kuzma teaches the tip member recited in Applicants’ claim 1. Rather, the Examiner states that “Kuzma discloses the invention as claimed including a flexible tip, but *fails to teach a conical tapered portion . . .*” (See, Office Action, page 6; emphasis added.) Thus, while the Examiner asserts that Kuzma teaches a tip that allegedly has one feature of the recited tip member, the Examiner has not articulated a finding that Kuzma teaches “a tip member comprising a *flexible conical tapered portion . . .* [that] prevents substantial foldover of said tip.” (See, Applicants’ claim 1, above; emphasis added.) Additionally, Applicants submit that the Examiner fails to assert that Charvin teaches the tip member recited in Applicants’ claim 1. In attempting to cure the above-noted deficiency of Kuzma, the Examiner states that “Charvin teaches that it is known to have a conical tapering at the distal end of an electrode array . . .” (See, Office Action, page 6.) However, Applicants submit that the Examiner fails to articulate a finding that Charvin teaches “a tip member comprising a *flexible* conical tapered portion . . . [that] prevents substantial foldover of said tip.” (See, Applicants’ claim 1, above; emphasis added.)

20. Thus, Applicants submit that the Examiner has failed to articulate at least the first finding that the Examiner must make in order to rely on “[c]ombining prior art elements according to known methods of yield predictable results.” (See, MPEP § 2143.) With regard to this exemplary rationale, the MPEP states that “*[i]f any of these findings cannot be made, then this rationale cannot be used* to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.” (See, MPEP § 2143(A); emphasis added.) Accordingly, Applicants submit that the Examiner’s rejection of claim 1 under 35 U.S.C. 103 over Kuzma and Charvin is improper.

21. For at least the reasons set forth above, Applicants submit that the Examiner’s proposed combination of Kuzma and Charvin fails to render obvious “a tip member comprising a flexible conical tapered portion . . . dimensioned and shaped such that said conical tapered portion of said tip member prevents substantial foldover of said tip when a deflection/impact force is applied to said tip member during implantation into the cochlea,” as recited in Applicants’ claim

1. Thus, Applicants respectfully request that this rejection of claim 1 be reconsidered and withdrawn.
22. Additionally, Applicants' claim 24 recites "mounting a flexible conical tapered tip member on a distal end of said elongate member . . . wherein said conical tapered portion of said tapered tip member is dimensioned and shaped such that said conical tapered portion of said tip member prevents substantial foldover of said tip." Thus, Applicants respectfully request that this rejection of claim 24 be reconsidered and withdrawn at least for reasons similar to those set forth above with regard to claim 1.
23. In addition, Applicants' claim 59 recites "a tip member comprising a flexible conical tapered portion extending distally from a distal end of said elongate carrier member, said conical tapered portion of said tip member is dimensioned and shaped such that said tip member prevents substantial foldover of said tip member." Thus, Applicants respectfully request that this rejection of claim 59 be reconsidered and withdrawn at least for reasons similar to those set forth above with regard to claim 1.

***Rejection of claim 29 under §103***

24. As noted above, the Examiner rejected claim 29 under 35 U.S.C. § 103 as allegedly unpatentable over Kuzma in view of Charvin. Applicants respectfully request that this rejection be reconsidered and withdrawn for at least the following reasons.
25. Applicants' claim 29 recites "a flexible conical tapered tip member . . . dimensioned and shaped such that said tip member causes at least a portion of said tip member to operate as a constant-strength cantilever beam when the deflection/impact forces are applied to said tip member during implantation." Applicants respectfully submit that the Examiners proposed combination of Kuzma and Charvin fails to render obvious the above-quoted limitation of claim 29.
26. For the Examiner's benefit, Applicants note that Applicants' specification states that "a tip member that has uniform bending stress distribution may be envisioned as ***a constant-strength cantilever beam*** where bending stresses throughout the beam are equal to those at the fixed end, that is, the junction of the tip member with the elongate member on which the tip member is

mounted..” (See, Applicants’ specification, para. 27; emphasis added.) Thus, Applicants submit that the definition of “constant-strength cantilever beam,” as recited in Applicants’ claim 29, is a beam “where bending stresses throughout the beam are equal to those at the fixed end.” (See, Applicants’ specification, para. 27.)

27. In rejecting Applicants’ claim 29, the Examiner states that “Kuzma discloses a tip member (Fig. 4, 37) that is made of LSR-25 supported by the electrode array that is made of LSR-70 (Col. 11, line 22-50). LSR 25 and LSR-70 have substantially the same flexibility with LSR-70 being slightly stiffer.” (See, Office Action, page 5.) After quoting a definition of the word “cantilever”, the Examiner then states “[a]ccordingly, the device disclosed by Kuzma sufficiently meets this limitation through the use of a stiffer carrier array body composed of LSR-70.” (See, Office Action, page 5.)

28. First, Applicants note that claim 29 does not recite merely a “cantilever beam”, but a “constant-strength cantilever beam.” (See, Applicants’ claim 29, above.) Second, Applicants submit that the Examiner has failed to show that soft tip 37, when modified based on Charvin to have a conical tapering shape, is “a constant-strength cantilever beam where bending stresses throughout the beam are equal to those at the fixed end.” (See, Applicants’ specification, para. 27. See also, Office Action, page 6.)

29. Applicants note that the MPEP states that “[t]he examiner bears the initial burden of ***factually supporting*** any *prima facie* conclusion of obviousness.” (See, MPEP § 2142; emphasis added.) However, Applicants submit that the Examiner has failed to provide adequate factual support for concluding that the proposed combination of Kuzma and Charvin render obvious claim 29. Moreover, if the Examiner is relying on his own personal knowledge, Applicant requests that the Examiner provide an affidavit in support of the above-quoted statements under 37 C.F.R. 1.104(d)(2).

30. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.



***Dependent claims***

31. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

32. In addition, as noted above, the Examiner rejected claim 20 as allegedly unpatentable over a proposed combination of Kuzma and Charvin. However, Applicants submit that the proposed combination of Kuzma and Charvin fails to render obvious dependent claim 20 for at least the following additional reason.

33. Applicants' claim 20 recites "[t]he device of claim 1, wherein said tip member has substantially uniform bending stress distribution in an axial direction." Applicants respectfully submit that the Examiners proposed combination of Kuzma and Charvin fails to render obvious the above-quoted limitation of claim 20.

34. For the Examiner's benefit, Applicants note that Applicants' specification states that

For the purposes of the present invention the term "uniform bending stress distribution" refers to the conventional meaning of the term uniform bending stress distribution. For example, a tip member that has uniform bending stress distribution may be envisioned as a constant-strength cantilever beam ***where bending stresses throughout the beam are equal to those at the fixed end***, that is, the junction of the tip member with the elongate member on which the tip member is mounted. (See, Applicants' specification, para. 27; emphasis added.)

In rejecting Applicants' claim 29, the Examiner states that "the Kuzma reference teaches of a system wherein the tip member inherently has a substantially uniform bending stress distribution in an axial direction, since the tip is of one material and circular and therefore had uniform bending stress (see for example Figure 4)." (See, Office Action, page 5.)

35. However, Applicants submit that the Examiner has failed to show that soft tip 37, ***when modified*** based on Charvin to have a conical tapering shape, inherently has a substantially uniform bending stress distribution. Applicants note that "[t]he examiner bears the initial burden of ***factually supporting*** any *prima facie* conclusion of obviousness." (See, MPEP §

2142; emphasis added.) However, Applicants submit that the Examiner has failed to provide adequate factual support for concluding that the proposed combination of Kuzma and Charvin render obvious claim 20. Moreover, if the Examiner is relying on his own personal knowledge, Applicant requests that the Examiner provide an affidavit in support of the above-quoted statements under 37 C.F.R. 1.104(d)(2).

36. For at least the additional reason set forth above, Applicants submit that the Examiner's proposed combination of Kuzma and Charvin fails to render obvious Applicants claim 20. Thus, Applicants respectfully request that the stated rejection of claim 20 under 35 U.S.C. § 103 over Kuzma and Charvin be reconsidered and withdrawn.

### ***Conclusion***

37. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

38. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

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Respectfully submitted,

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